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10/517,704

08/30/2005

Gerd Dahms

BPD-0014

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EXAMINER

HOLT, ANDRIAE M

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

12/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/517,704 | Applicant(s) DAHMS, GERD | |
| | Examiner Andriae M. Holt | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's arguments filed August 10, 2009. Claims 17-21 and 23 are pending in the application. Claim 17 has been amended. Claims 17-21 and 23 will presently be examined to the extent they read on the elected subject matter of record.

Status of the Claims

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are reiterated. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

The rejection of claims 17-21 and 23 under 35 U.S.C. 103(a) as being unpatentable over Mather et al. (WO 96/39119) **is maintained**.

The rejection of claims 17-20 and 23 under 35 U.S.C. 103(a) as being unpatentable over Zuckert et al. (US 3,979,346) **is maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mather et al. (WO 96/39119).

Applicant's Invention

Applicant claims an ether alcohol/polyol-in-oil emulsion comprising at least one ether alcohol of the general formula (I) $R_1-O-[EO-]_n H$ where R_1 is C1-3-alkyl, n is on average 7 to 15, and EO is building blocks derived from ethylene oxide, in an oil-immiscible ether alcohol/polyol phase, an oil phase and at least one emulsifier.

Applicant further claims that a cosmetic and/or pharmaceutical and/or agrochemical active ingredient is dissolved in the ether alcohol/polyol phase.

***Determination of the scope of the content of the prior art
(MPEP 2141.01)***

Mather et al. teach the invention relates to topical compositions containing azelaic acid and glycol and more particularly to new and improved compositions containing stabilized and completely solubilized azelaic acid (page 1, lines 7-10). Mather et al. further teach that another objective is to provide lower, yet effective concentrations of a topical azelaic acid formulation that is less likely to irritate the skin of the user (page 5, lines 5-7). Mather et al. teach that azelaic acid, a straight chain dicarboxylic acid with 9 carbons, has limited solubility in water and commonly used cosmetic oils. Mather et al. teach that low levels of azelaic acid may be completely dissolved in glycol from about 20% (w/w) to about 60% (w/w) (claim 20, 50 % weight, instant invention) and remain in stable solution (page 4, lines 20-25). Mather et al. teach that the glycol utilized may be one or more of the following, including methoxypolyethylene glycol (page 4, lines 25-28) (ether alcohol, methanol ethoxylate, claims 17 and 20, instant invention). Mather et al. teach that if lower levels of azelaic acid are used, the glycol level can be reduced and conventional emulsions with cosmetic oils formed (page 6, lines 19-24).

Mather et al. teach on page 8, in example 3, lines 15-34, that an emulsion with commonly used cosmetic oils is made by mixing azelaic acid with dipropylene glycol and distilled water, which the mixture is then heated to 70° C until a clear solution results (claim 21, comprises a pharmaceutical active, instant invention). Mather further teaches that in a separate container C12-C15 benzoate, isododecane, cyclomethicone, stearyl alcohol (claim 17, emulsifier, instant invention), a commercial mixture of glyceryl stearate and PEG-100 stearate (ARLACEL 165) and a commercial mixture of isopropylparaben, isobutylparaben and butylparaben (LIQUAPAR OIL)(claim 17, oil, instant invention). Mather et al. teach that to this mixture the azelaic acid-dipropylene glycol-water mixture is added and the whole mixed while maintaining the temperature at 70° C. Mather et al. further teach the mixture is allowed to cool to 45° C.

***Difference between the prior art and the claims
(MPEP 2141.02)***

Mather et al. do not teach the use of the specific ether alcohol of general formula (I), wherein the number of ethylene oxide units is 7.

***Finding of obviousness/Rationale and Motivation
(MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Mather et al. and use specific ether alcohol of general formula wherein the number of ethylene oxide units is 7 in the compositions as taught by Mather et al. Mather et al. teach the use of glycol derivatives to prepare emulsions containing a pharmaceutical agent, particularly methoxypolyethylene glycol, which is in the general class of ether alcohols represented by compounds of formula I. One skilled

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in the art at the time the invention was made would have been motivated to use methoxypolyethylene glycol with a reasonable expectation of success since Mather et al. teach methoxypolyethylene glycol and dipropylene glycol can be used as the glycol in azelaic acid compositions. Therefore, it would have been prima facie obvious to substitute one glycol such as methoxypolyethylene glycol for another glycol such as dipropylene glycol since the prior art establishes methoxypolyethylene glycol and dipropylene glycol are all functional equivalents.

In reference to the number of ethylene oxide units in the ether alcohol being 7, it would have been obvious to the skilled artisan to use a methoxypolyethylene glycol with 7 ethylene oxide units as a matter of routine experimentation and optimization. As Mather et al. does not specify the number of ethylene oxide units that can be used in the composition, the skilled artisan would deem the use of methoxypolyethylene glycol with 7 ethylene oxide units a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited references.

Response to Arguments

Applicant's arguments filed August 10, 2009 have been fully considered but they are not persuasive. Applicant argues Mather does not teach or suggest the methoxypolyethylene glycol wherein "n" is on average 7 to 15 ethylene oxide units. In response to Applicant's arguments, it is reasonable to conclude that any chain length

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would provide the expected results. Since a particular parameter must first be recognized as a result-effective variable, absent evidence that the narrow range of "n" is on average 7 to 15 exhibits unexpected results, the skilled artisan would expect any and all ranges of the chain length would provide the expected results. Therefore, absent evidence of unexpected results, the use of a methoxypolyethylene glycol of any chain length would be expected to work in the formulation of the emulsion. The claims remain rejected.

Claims 17-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zuckert et al. (US 3,979,346).

Applicant's Invention

Applicant claims an ether alcohol/polyol-in-oil emulsion comprising at least one ether alcohol of the general formula (I) $R_1-O-[EO]_n H$ where R_1 is C1-3-alkyl, n is on average 7 to 15, and EO is building blocks derived from ethylene oxide, in an oil-immiscible ether alcohol/polyol phase, an oil phase and at least one emulsifier.

Applicant further claims the addition of at least one aqueous phase.

Determination of the scope of the content of the prior art (MPEP 2141.01)

Zuckert et al. disclose emulsion systems for preparing aqueous dispersions of alkyd resins; aqueous dispersions of alkyd resins, and a process of making the dispersions (Abstract). Zuckert et al. disclose the emulsifier system is a combination of a) at least one non-ionic emulsifier, the hydrophobic part of which consists of two or more radicals of unsaturated fatty acids and/or fatty alcohols with an iodine number

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between 130 and 200 (oil), and the hydrophilic part consists of chains of polyethylene glycol and/or monomethoxypolyethylene glycol with 6 - 100 ethylene oxide units (ether alcohol of formula I, n is 7 to 15, ether alcohol/polyol phase); and b) at least one anionic emulsifier, the hydrophobic part of which consists of two or more radicals of unsaturated fatty acids and/or fatty alcohols with an iodine number of between 130 and 200, and the hydrophilic part consists of carboxy groups, at least 50 percent of which are dissociated by the ammonia utilized. Zuckert et al. disclose that minor amounts of organic solvents can be employed (aqueous phase) (col. 2, lines 53-68-col. 3, lines 1-7) . Zuckert et al. disclose in example E. 01 (nonionic emulsifier) that 880 g of linseed oil (oil) are reacted with a total of 200 g of maleic anhydride to form an adduct. The linseed-maleic anhydride-adduct (8.8: 2) obtained is mixed with 36 g of water and a catalytic quantity of triethylamine and held at reflux for 3 hours. The components are mixed 1: 3 (opened adduct: ethylene oxide). The resulting product is highly viscous yellow oil with an ethylene oxide content of 75 percent by weight. Zuckert et al. further disclose in example E. 02 a mixed nonionic-anionic emulsifier. 1080 g linseed-maleic anhydride-adduct (8.8: 2) (oil, emulsifier) of E. 01 are reacted at with 2200 g of methoxypolyethylene glycol (molecular weight about 1100) (ether alcohol/polyol phase) until the acid value has fallen to 30 - 35 mg KOH/g. The resultant yellow wax-like mass has an ethylene oxide content of 67 percent by weight (col. 6, lines 1-22). Zuckert et al. disclose more examples of the preparation of nonionic emulsifiers in examples E.06 and E.07 (col. 7, lines 7-20). Zuckert et al. disclose in Table II, cols. 9-10 lines 11-65,

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dispersion blends, particularly, A2 E.06/6% (oil and ether alcohol/polyol phase), E.09/1% (anionic emulsifier) and 1.25%NH₃ (aqueous phase).

***Difference between the prior art and the claims
(MPEP 2141.02)***

Zuckert et al. do not teach specific examples where the number of ethylene oxide units is 7.

***Finding of obviousness/Rationale and Motivation
(MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Zuckert et al. and use specific ether alcohol of general formula wherein the number of ethylene oxide units is 7 in the emulsion systems taught by Zuckert et al. One skilled in the art at the time the invention was made would have been motivated to use methoxypolyethylene glycol that has 7 ethylene oxide units because Zuckert et al. specifically teach that the monomethoxypolyethylene glycol used in the system has 6-100 ethylene units. In addition the skilled artisan would have used the monomethoxypolyethylene glycol that has 7 ethylene oxide units as a matter of routine experimentation and optimization. As Zuckert et al. does not specify the number of ethylene oxide units that can be used in the composition, the skilled artisan would deem the use of methoxypolyethylene glycol with 7 ethylene oxide units a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited references.

Response to Arguments

Applicant's arguments filed August 10, 2009 have been fully considered but they are not persuasive. Applicant argues that Zuckert does not teach or suggest an emulsion containing Applicant's claim 17 ether alcohol and that Zuckert's nonionic surfactants include fatty acid residues and maleic anhydride residues that are excluded from Applicant's claim 17 ether alcohol. In response to Applicant's argument, Zuckert specifically teaches that the alkyd resin is dispersed in a dispersing agent or emulsifier system. The emulsifier system consists of at least one non-ionic emulsifier, the hydrophobic part of which consists of two or more radicals of unsaturated fatty acids and/or fatty alcohols with an iodine number between 130 and 200 (oil), and the hydrophilic part consists of chains of polyethylene glycol and/or monomethoxypolyethylene glycol with 6 - 100 ethylene oxide units (ether alcohol of formula I, n is 7 to 15, ether alcohol/polyol phase); and b) at least one anionic emulsifier, the hydrophobic part of which consists of two or more radicals of unsaturated fatty acids and/or fatty alcohols with an iodine number of between 130 and 200, and the hydrophilic part consists of carboxy groups, at least 50 percent of which are dissociated by the ammonia utilized. Zuckert et al. disclose that minor amounts of organic solvents can be employed (aqueous phase). Therefore, it would have been obvious to the skilled artisan that the monomethoxypolyethylene glycol having 6-100 ethylene oxide units is used to

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form an emulsion. The use of the emulsion in a reaction is an intended use which has no patentable weight.

In response to the fact that Zuckert's nonionic surfactants include fatty acid residues and maleic anhydride residues, Applicant uses open terminology, "comprising", which leads the formulation open to the inclusion of other components including fatty acid residues and maleic anhydride residues.

In response to the argument that Zuckert does not teach or suggest the methoxypolyethylene glycol wherein "n" is on average 7 to 15 ethylene oxide units, it is reasonable to conclude that any chain length would provide the expected results. Since a particular parameter must first be recognized as a result-effective variable, absent evidence that the narrow range of "n" is on average 7 to 15 exhibits unexpected results, the skilled artisan would expect any and all ranges of the chain length would provide the expected results. Therefore, absent evidence of unexpected results, the use of a monomethoxypolyethylene glycol having with 6-100 ethylene oxide units would be expected to work in the formulation of the emulsion.

None of the claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
Art Unit 1616

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/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616